

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

REPLIGEN CORPORATION and
THE REGENTS OF THE UNIVERSITY OF
MICHIGAN,

Plaintiffs,

v.

BRISTOL-MYERS SQUIBB COMPANY,

Defendant.

Case No. 2:06-CV-004-TJW

JURY TRIAL DEMANDED

AMENDED COMPLAINT

For their Amended Complaint plaintiffs Repligen Corporation (“Repligen”) and The Regents of the University of Michigan (“University of Michigan”) (collectively “Plaintiffs”), by and through the undersigned attorneys, allege as follows:

THE PARTIES

1. Plaintiff Repligen is a corporation organized under the laws of the state of Delaware, with its principal place of business at 41 Seyon Street, Building #1, Suite 100, Waltham, MA 02453.
2. Plaintiff University of Michigan is a constitutional corporation of the state of Michigan located in Ann Arbor, Michigan.
3. On information and belief, defendant Bristol-Myers Squibb Company (“Bristol-Myers”) is a corporation organized under the laws of the state of Delaware, with its principal place of business at 345 Park Avenue, New York, NY 10154-0037.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

5. Subject matter jurisdiction is proper in this Court under 28 U.S.C. §§ 1331 and 1338.

6. This Court has personal jurisdiction over Bristol-Myers because, among other things, BMS regularly does business in this judicial district and further has appeared and answered the original complaint in this case.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENT-IN-SUIT

8. United States Patent No. 6,685,941 (“the ’941 patent”), entitled “Methods Of Treating Autoimmune Disease Via CTLA-4Ig,” was duly and legally issued by the United States Patent and Trademark Office to Craig B. Thompson and Carl H. June on February 3, 2004.

9. The ’941 patent is assigned to the University of Michigan and the United States of America as represented by the Secretary of the Navy.

10. Based on agreements with University of Michigan and United States Department of the Navy, Repligen is an exclusive licensee under the ’941 patent and has the right to sue for infringement of the ’941 patent.

COUNT I

DIRECT INFRINGEMENT OF THE ’941 PATENT

11. Plaintiffs re-allege and incorporate herein by reference the allegations stated in paragraphs 1-10 of this Complaint.

12. Bristol-Myers filed or caused to be filed with the United States Food and Drug Administration (“FDA”) a Biologic License Application (“BLA”) #125118, seeking approval to market fusion protein abatacept for use in treating rheumatoid arthritis. Bristol-Myers has adopted the brand name ORENCIA® for abatacept.

13. On or about December 23, 2005, the FDA approved abatacept for the treatment of rheumatoid arthritis but not for any other use.

14. Using abatacept to treat rheumatoid arthritis infringes the ’941 patent.

15. On information and belief, Bristol-Myers is manufacturing abatacept and contracting with others to manufacture abatacept to treat rheumatoid arthritis.

16. On information and belief, Bristol-Myers is importing, or contracting with others to import, abatacept to treat rheumatoid arthritis.

17. On information and belief, Bristol-Myers is selling and offering to sell abatacept to treat rheumatoid arthritis.

18. On information and belief, Bristol-Myers is instructing health care providers including doctors to administer abatacept to patients having rheumatoid arthritis.

19. On information and belief, Bristol-Myers is administering abatacept to patients having rheumatoid arthritis, or causing such administration.

20. Bristol-Myers now has made ORENCIA® commercially available for treating rheumatoid arthritis and, on information and belief, has for some time been making extensive preparation for offers for sale and sale of abatacept for the treatment of rheumatoid arthritis. For example, in the Form 10-Q Bristol-Myers filed with the Securities and Exchange Commission for the quarter ending September 30, 2005, BMS stated that abatacept already constituted a “significant proportion” of its \$125 million inventory.

21. An actual and justiciable controversy exists, as Bristol-Myers's importation, use, offers to sell and selling abatacept is directly infringing the '941 patent.

COUNT II

CONTRIBUTORY AND INDUCEMENT OF INFRINGEMENT OF THE '941 PATENT

22. Plaintiffs re-allege and incorporate herein by reference the allegations stated in paragraphs 1-21 of this Complaint.

23. On information and belief, Bristol-Myers, by offering abatacept for sale for use in treating rheumatoid arthritis and/or by otherwise supplying abatacept for use in treating rheumatoid arthritis, is presently actively inducing infringement of and contributorily infringing the '941 patent, all to Plaintiffs' damage.

24. On information and belief, Bristol-Myers will continue to actively induce infringement of and contributorily infringe the '941 patent unless enjoined by this Court.

25. On information and belief, by administering abatacept to patients having rheumatoid arthritis, or causing such administration, Bristol-Myers infringes the '941 patent and will continue to infringe the '941 patent unless enjoined by this Court.

26. On information and belief, Bristol-Myers's infringement, active inducement of infringement, and contributory infringement have been willful and will continue to be willful, making this case exceptional and entitling Plaintiffs to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment against Bristol-Myers:

(1) that Bristol-Myers's conduct in importing, using, offering to sell or selling abatacept for treatment of rheumatoid arthritis during the term of the '941 patent infringes, contributorily infringes, and actively induces the infringement of the '941 patent;

(2) that a permanent injunction is appropriate and proper, enjoining and restraining Bristol-Myers and its agents, servants, employees, affiliates, divisions, and subsidiaries, and those in association with them, from (a) unlicensed use of abatacept for treatment of rheumatoid arthritis; (b) unlicensed inducement of others to use abatacept for treatment of rheumatoid arthritis; and (c) unlicensed importation, offers to sell, or sales of abatacept for use in treating rheumatoid arthritis;

(5) an award of damages sufficient to compensate for such past infringement;

(6) an award of increased damages pursuant to 35 U.S.C. § 284;

(7) an award of all costs of this action, including attorneys' fees and interest; and

(8) such other and further relief, at law or in equity, to which Plaintiffs are justly entitled.

JURY DEMAND

Plaintiffs demand a jury trial on all issues triable by a jury.

Respectfully submitted,

Dated: December 21, 2006

By: /s/ Sam Baxter
Samuel F. Baxter (Bar No. 01938000)
McKOOL SMITH P.C.
505 East Travis Street, Suite 105
Marshall, Texas 75670
(903) 927-2111
(903) 927-2622

Of Counsel:

Ruffin B. Cordell (Bar No. 04820550)
Ahmed J. Davis
FISH & RICHARDSON P.C.
1425 K Street, N.W., 11th Floor
Washington, DC 20005
(202) 783-5070 (phone)
(202) 783-2331 (facsimile)

Robert E. Hillman
Gregory A. Madera
Tawen Chang
Ramon K. Tabtiang
FISH & RICHARDSON P.C.
225 Franklin Street
Boston, MA 02110
(617) 542-5070 (phone)
(617) 542-8906 (facsimile)

Attorneys for REPLIGEN CORPORATION
and THE REGENTS OF THE UNIVERSITY
OF MICHIGAN

Fred H. Nemeth
REPLIGEN CORPORATION
41 Seyon Street
Building #1, Suite 100
Waltham, MA 02453
Tel: (781) 250-0111
Fax: (781) 250-0115

Attorney for REPLIGEN CORPORATION

J. Michael Huget
BUTZEL LONG
350 South Main Street
Suite 300
Ann Arbor, MI 48104
Tel: (734)-995-3110
Fax: (734)-995-1777

Attorney for THE REGENTS OF THE
UNIVERSITY OF MICHIGAN

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing documents was served on counsel of record via the Court's ECF system on December 21, 2006.

/s/ Sam Baxter